

# Exhibit A16

UNITED STATES DISTRICT COURT  
DISTRICT OF MASSACHUSETTS

IN RE: NEW ENGLAND  
COMPOUNDING PHARMACY, INC.  
PRODUCTS LIABILITY LITIGATION

MDL No. 1:13-md-2419-FDS

This Document Relates to:

All actions pending against Saint Thomas  
Outpatient Neurosurgical Center, LLC,  
and its affiliates including:

1:13-cv-12234-FDS May et al v.  
Ameridose, LLC et al  
1:13-cv-12238-FDS Carman et al v.  
Ameridose, LLC et al  
1:13-cv-12305-FDS Wiley et al v.  
Ameridose, LLC et al  
1:13-cv-12311-FDS Schulz et al v.  
Ameridose, LLC et al  
1:13-cv-12315-FDS Hester et al v.  
Ameridose, LLC et al  
1:13-cv-12426-FDS Davis et al v.  
Ameridose, LLC et al  
1:13-cv-12429-FDS Bequette et al v.  
Ameridose, LLC et al  
1:13-cv-12430-FDS Norwood et al v.  
Ameridose, LLC et al  
3:13-cv-00918 Ziegler et al v. Ameridose,  
LLC et al  
3:13-cv-00919 Martin v. Ameridose, LLC  
et al  
3:13-cv-00923 Reed v. Ameridose, LLC et  
al  
3:13-cv-00929 Brinton v. Ameridose, LLC  
et al  
3:13-cv-00930 Lovelace v. Ameridose,  
LLC et al  
3:13-cv-00931 Ragland v. Ameridose, LLC  
et al  
3:13-cv-00932 Slatton et al v. Ameridose,  
LLC et al  
3:13-cv-00933 Rybinski v. Ameridose,  
LLC et al

3:13-cv-00934 Lemberg et al v.	)
Ameridose, LLC et al	)
3:13-cv-00935 Ruhl et al v. Ameridose,	)
LLC et al	)
3:13-cv-00938 McElwee v. Ameridose,	)
LLC et al	)
3:13-cv-00940 Robnett et al v. Ameridose,	)
LLC et al	)
3:13-cv-00941 Sharer et al v. Ameridose,	)
LLC et al	)
3:13-cv-00942 Johnson et al v. Ameridose,	)
LLC et al	)
3:13-cv-00943 Knight v. Ameridose, LLC	)
et al	)
3:13-cv-00951 Knihtila v. Ameridose, LLC	)
et al	)
3:13-cv-00952 Sellers et al v. Ameridose,	)
LLC et al	)
3:13-cv-00953 Barger et al v. Ameridose,	)
LLC et al	)
3:13-cv-00954 Lodowski et al v.	)
Ameridose, LLC et al	)
3:13-cv-00961 Skelton et al v. Ameridose,	)
LLC et al	)
3:13-cv-00962 Chambers et al v.	)
Ameridose, LLC et al	)
3:13-cv-00963 Hill et al v. Ameridose,	)
LLC et al	)
3:13-cv-00964 Mathias v. Ameridose, LLC	)
et al	)
3:13-cv-00965 Settle et al v. Ameridose,	)
LLC et al	)
3:13-cv-00966 Miller v. Ameridose, LLC	)
et al	)
3:13-cv-00967 Noble et al v. Ameridose,	)
LLC et al	)
3:13-cv-00968 Eggleston et al v.	)
Ameridose, LLC et al	)
3:13-cv-00969 Meeker et al v. Ameridose,	)
LLC et al	)
3:13-cv-00970 Scott et al v. Ameridose,	)
LLC et al	)
3:13-cv-00971 McCullouch et al v.	)
Ameridose, LLC et al	)
3:13-cv-00972 McKee et al v. Ameridose,	)
LLC et al	)

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3:13-cv-00973 Kirby v. Ameridose, LLC et al	)
3:13-cv-00975 Richards v. Ameridose, LLC et al	)
3:13-cv-00977 Youree et al v. Ameridose, LLC et al	)
3:13-cv-00978 Koonce et al v. Ameridose, LLC et al	)
3:13-cv-00979 Pelters et al v. Ameridose, LLC et al	)
3:13-cv-00984 Besaw et al v. Ameridose, LLC et al	)
3:13-cv-00985 Ferguson et al v. Ameridose, LLC et al	)
3:13-cv-00986 Hurt et al v. Ameridose, LLC et al	)
3:13-cv-00987 Wanta et al v. Ameridose, LLC et al	)
3:13-cv-00988 Russell et al v. Ameridose, LLC et al	)
3:13-cv-00989 Pruitt et al v. Ameridose, LLC et al	)
3:13-cv-00992 Young v. Ameridose, LLC et al	)
3:13-cv-00993 Sullivan et al v. Ameridose, LLC et al	)
3:13-cv-01033 Barnard v. Ameridose, LLC et al	)
3:13-cv-01032 Berry v. Ameridose, LLC et al	)

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**PLAINTIFFS' STEERING COMMITTEE'S FIRST SET OF REQUESTS  
FOR ADMISSIONS TO DEFENDANTS AND CORRESPONDING  
INTERROGATORY**

The Plaintiffs' Steering Committee, pursuant to Federal Rules of Civil Procedure 26, 33, and 36, respectfully propounds this Interrogatory and these Requests for Admission to the Defendants Saint Thomas Outpatient Neurosurgical Center, LLC, Howell Allen Clinic, John Culclasure, M.D., Debra Schamberg, R.N., Saint Thomas West Hospital (formerly known as St.

Thomas Hospital), Saint Thomas Network and Saint Thomas Health to be answered within the time prescribed by law.

### **DEFINITIONS**

As used herein, the following terms mean:

“Saint Thomas Neurosurgical” means Saint Thomas Outpatient Neurosurgical Center, LLC.

“Howell Allen Clinic” means Howell Allen Clinic A Professional Corporation.

“NECC” means New England Compounding Pharmacy, Inc. d/b/a New England Compounding Center.

“MPA” means methylprednisolone acetate.

“Dr. Culclasure” means John Culclasure, M.D.

“Ms. Schamberg” means Debra Schamberg, R.N.

“St. Thomas Hospital” means Saint Thomas West Hospital, formerly known as St. Thomas Hospital.

### **INTERROGATORY**

1. If your response to any of the following Requests for Admission is other than an unqualified admission, for each such Request for Admission state all facts (not opinions) that you contend support in any manner your refusal to admit or your qualification of your admission, identify all documents, notes, reports, memoranda, electronic and/or tape recordings, photographs, oral statements, or any other tangible or intangible thing that supports in any manner your refusal to admit or your qualification of your admission, the name and address of the custodian of all tangible things identified above, and the name and address of all persons,

including consultants and experts, purporting to have knowledge or factual data upon which you base your refusal to admit or the qualification of your admission.

**RESPONSE:**

**REQUESTS FOR ADMISSION**

1. Admit that in 2002, the CDC published a report regarding at least two cases of fungal meningitis arising from contaminated medication used in epidural injections. The report stated that “purchasers of pharmaceuticals should determine if supplies are provided from a compounding pharmacy that . . . follows appropriate measures to ensure that injectable products are free of contamination.” A copy of that published report is attached as Exhibit 1.

**RESPONSE:**

2. Admit that Exhibit 1 is “a record or statement of a public office” as that term is used in Federal Rule of Evidence 803(8).

**RESPONSE:**

3. Admit that Exhibit 1 sets out “factual findings from a legally authorized investigation” as that term is used in Federal Rule of Evidence 803(8).

**RESPONSE:**

4. Admit that Exhibit 1’s source of information does not “indicate a lack of trustworthiness” as that term is used in Federal Rule of Evidence 803(8).

**RESPONSE:**

5. Admit that, as to Exhibit 1, no other circumstance “indicate[s] a lack of trustworthiness” as that term is used in Federal Rule of Evidence 803(8).

**RESPONSE:**

6. Admit that on March 24, 2005, USA Today published a front page article with the following headline: “**Safety concerns grow over pharmacy-mixed drugs.**” A true and correct copy of the text from that article is attached as Exhibit 2.

**RESPONSE:**

7. Admit that in 2006, the FDA conducted a survey of compounded drug products. They collected thirty-six samples from compounding pharmacies across the United States during unannounced visits. Twelve of the 36 samples (33%) failed analytical testing. The FDA survey stated “poor quality compounded drugs are a serious public health concern, as improperly compounded products have been linked to grave adverse events, including deaths.” A true and correct copy of the FDA’s report titled *2006 Limited FDA Survey of Compounded Drug Products* is attached as Exhibit 3.

**RESPONSE:**

8. Admit that Exhibit 3 is “a record or statement of a public office” as that term is used in Federal Rule of Evidence 803(8).

**RESPONSE:**

9. Admit that Exhibit 3 sets out “factual findings from a legally authorized investigation” as that term is used in Federal Rule of Evidence 803(8).

**RESPONSE:**

10. Admit that Exhibit 3’s source of information does not “indicate a lack of trustworthiness” as that term is used in Federal Rule of Evidence 803(8).

**RESPONSE:**

11. Admit that, as to Exhibit 3, no other circumstance “indicate[s] a lack of trustworthiness” as that term is used in Federal Rule of Evidence 803(8).

**RESPONSE:**

12. In May 2007, the FDA published an article titled “The Special Risks of Pharmacy Compounding.” A true and correct copy of that article is attached as Exhibit 4.

**RESPONSE:**

13. Admit that Exhibit 4 is “a record or statement of a public office” as that term is used in Federal Rule of Evidence 803(8).

**RESPONSE:**

14. Admit that Exhibit 4 sets out “factual findings from a legally authorized investigation” as that term is used in Federal Rule of Evidence 803(8).

**RESPONSE:**



15. Admit that Exhibit 4's source of information does not "indicate a lack of trustworthiness" as that term is used in Federal Rule of Evidence 803(8).

**RESPONSE:**

16. Admit that, as to Exhibit 4, no other circumstance "indicate[s] a lack of trustworthiness" as that term is used in Federal Rule of Evidence 803(8).

**RESPONSE:**

17. Admit that in 2010, the FDA posted an educational video on YouTube regarding compounded drugs. That educational video is found on the World Wide Web at [http://www.youtube.com/watch?v=kif\\_rmtIQb0](http://www.youtube.com/watch?v=kif_rmtIQb0).

**RESPONSE:**

18. Admit that on November 5, 2010, the American Society of Anesthesiologists, the American Society of Health-System Pharmacists ("ASHP") and other medical societies published a joint report regarding drug shortages. That report included an article written by the ASHP stating as follows:

Compounding pharmacies have also pursued the production of drugs that are in short supply. Caution is warranted because preparations from these pharmacies may not meet applicable state or federal standards (e.g., United States Pharmacopeia chapter 797 or FDA labeling requirements). The sources of raw materials used by compounding pharmacies have been questioned, and apparent lapses in quality control have resulted in serious patient injury, including death.

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Compounding pharmacies may also present patient risks; several deaths have been associated with improperly sterilized compounded products.

An excerpt from that joint report is attached as Exhibit 5.

**RESPONSE:**

19. Admit that on May 2012, the CDC published a report regarding fungal infections arising from medications obtained from a compounding pharmacy. That report advised that “contamination of compounded sterile preparations has caused outbreaks. Since 1990, FDA has learned of approximately 200 adverse events associated with 71 compounded products.” Portions of that report are attached as Exhibit 6.

**RESPONSE:**

20. Admit that Exhibit 6 is “a record or statement of a public office” as that term is used in Federal Rule of Evidence 803(8).

**RESPONSE:**

21. Admit that Exhibit 6 sets out “factual findings from a legally authorized investigation” as that term is used in Federal Rule of Evidence 803(8).

**RESPONSE:**

22. Admit that Exhibit 6’s source of information does not “indicate a lack of trustworthiness” as that term is used in Federal Rule of Evidence 803(8).

**RESPONSE:**

23. Admit that, as to Exhibit 6, no other circumstance “indicate[s] a lack of trustworthiness” as that term is used in Federal Rule of Evidence 803(8).

**RESPONSE:**

24. Admit that in 2010, the American Society of Health System Pharmacists published the “ASHP Guidelines on Outsourcing Sterile Compounding Services.” A true and correct copy of that publication is attached as Exhibit 7.

**RESPONSE:**

25. Admit that the American Society of Health System Pharmacists developed a “Contractor Assessment Tool” for healthcare organizations to use in conjunction with assessing compounding pharmacies. A true and correct copy of that assessment tool is attached as Exhibit 8.

**RESPONSE:**

26. Admit that in December 2011, the International Academy of Compounding Pharmacists published the “Compounding Pharmacy Assessment Questionnaire.” A true and correct copy of that questionnaire is attached as Exhibit 9.

**RESPONSE:**

27. Admit that NECC operated a compounding pharmacy in Framingham, Massachusetts on a site shared with a mattress recycling and/or garbage compacting operation.

**RESPONSE:**

28. Admit that NECC compounded MPA in so-called “clean rooms” that were filthy.

**RESPONSE:**

29. Admit that a leaky boiler stood in a pool of stagnant, dirty water at NECC’s compounding facility.

**RESPONSE:**

30. Admit that the autoclaves used to sterilize products at NECC were discolored, tarnished, and contained visible moisture.

**RESPONSE:**

31. Admit that the air vents in the NECC “clean” rooms were covered with dirt and white fuzz.

**RESPONSE:**

32. Admit that the metal shelf in the “clean” room used to prepare MPA was covered in a reddish-brown, cloudy substance.

**RESPONSE:**

33. Admit that Howell Allen Clinic is a neurosurgical group with its primary office located in Nashville, Tennessee.

**RESPONSE:**

34. Admit that Howell Allen Clinic owns a 50% interest in Saint Thomas Neurosurgical.

**RESPONSE:**

35. Admit that Saint Thomas Neurosurgical is a for-profit limited liability company.

**RESPONSE:**

36. Admit that Saint Thomas Neurosurgical's profits are distributed, in part, to Howell Allen Clinic.

**RESPONSE:**

37. Admit that Howell Allen Clinic refers patients to Saint Thomas Neurosurgical.

**RESPONSE:**

38. Admit that Howell Allen Clinic refers patients to Saint Thomas Neurosurgical for epidural steroid injections.

**RESPONSE:**

39. Admit that Saint Thomas Neurosurgical administers epidural steroid injections to patients for profit.

**RESPONSE:**

40. Admit that when Saint Thomas Neurosurgical distributes profits to Howell Allen Clinic, the owners of Howell Allen Clinic make more money.

**RESPONSE:**

41. Admit that Saint Thomas Neurosurgical is located on the 9<sup>th</sup> floor of the Medical Plaza East Building on the St. Thomas Hospital campus.

**RESPONSE:**

42. Admit that Saint Thomas Network owns a 50% interest in Saint Thomas Neurosurgical.

**RESPONSE:**

43. Admit that Saint Thomas Network is a company with no employees.

**RESPONSE:**

44. Admit that Saint Thomas Network is owned by Saint Thomas Health, the same entity that owns St. Thomas Hospital.

**RESPONSE:**

45. Admit that the CEO of St. Thomas Hospital is on the Board of Governors of Saint Thomas Neurosurgical.

**RESPONSE:**

46. Admit that the Medical Director of St. Thomas Hospital regularly attended Saint Thomas Neurosurgical's Board of Governors meetings.

**RESPONSE:**

47. Admit that Saint Thomas Neurosurgical conducted its Board of Governors meetings in the St. Thomas Hospital board room.

**RESPONSE:**

48. Admit that John Culclasure, M.D. was the Medical Director for Saint Thomas Neurosurgical in 2012.

**RESPONSE:**

49. Admit that John Culclasure, M.D. was an agent, employee or member of Howell Allen Clinic throughout 2012.

**RESPONSE:**

50. Admit that Debra Schamberg, R.N. was the Facilities Director for Saint Thomas Neurosurgical in 2012.

**RESPONSE:**

51. Admit that Debra Schamberg, R.N was an agent, employee or member of Howell Allen Clinic throughout 2012.

**RESPONSE:**

52. Admit that Saint Thomas Neurosurgical's Facility Director, Debra Schamberg, R.N., is an employee of Howell Allen Clinic.

**RESPONSE:**

53. Admit that Saint Thomas Neurosurgical's Medical Director, John Culclasure, M.D. is an employee of Howell Allen Clinic.

**RESPONSE:**

54. Admit that all persons working at Saint Thomas Neurosurgical in 2012 were employees of Howell Allen Clinic.

**RESPONSE:**

55. Admit that Debra Schamberg R.N. and John Culclasure, M.D. used Howell Allen Clinic email addresses in 2012.

**RESPONSE:**

56. Admit that all persons working at Saint Thomas Neurosurgical used Howell Allen Clinic email addresses in 2012.



**RESPONSE:**

57. Admit that Saint Thomas Neurosurgical's Facility Director, Debra Schamberg, is part of Howell Allen Clinic's Staff.

**RESPONSE:**

58. Admit that Scott Butler is the Chief Administrative Officer and/or CEO of Howell Allen Clinic.

**RESPONSE:**

59. Admit that Scott Butler reported to the *Tennessean* that Saint Thomas Neurosurgical started 12 years ago as a joint venture between Saint Thomas Network and Howell Allen Clinic.

**RESPONSE:**

60. Admit that Scott Butler reported to the *Tennessean* that Howell Allen Clinic manages the hiring and workers at Saint Thomas Neurosurgical.

**RESPONSE:**

61. Admit that Scott Butler reported to the *Tennessean* that Saint Thomas Network handles contracting, credentialing and finances at Saint Thomas Neurosurgical.

**RESPONSE:**

62. Admit that Gregory Lanford, M.D. is the registered agent for and president of Howell Allen Clinic.

**RESPONSE:**

63. Admit that Gregory Lanford, M.D. is the registered agent for Saint Thomas Neurosurgical.

**RESPONSE:**

64. Admit that Amanda Starr is an employee of Howell Allen Clinic. She works at Howell Allen Clinic's office location at 2011 Murphy Avenue, Suite 301, Nashville, Tennessee, 37203.

**RESPONSE:**

65. Admit that Amanda Starr signed several Domestic Return Receipts for certified mail packages addressed to Gregory Lanford, M.D., registered agent for Howell Allen Clinic and Saint Thomas Neurosurgical, in connection with this litigation.

**RESPONSE:**

66. Admit that Dr. Culclasure and Ms. Schamberg co-managed Saint Thomas Neurosurgical's day-to-day operations.

**RESPONSE:**

67. Admit that Dr. Culclasure and Ms. Schamberg were directly involved with and responsible for Saint Thomas Neurosurgical's decision to purchase MPA from NECC.

**RESPONSE:**

68. Admit that Saint Thomas Neurosurgical, Dr. Culclasure, and Ms. Schamberg made the decision to purchase MPA in bulk from NECC because it was the cheapest alternative.

**RESPONSE:**

69. Admit that Saint Thomas Neurosurgical did not use patient-specific individual prescriptions when buying MPA from NECC in bulk.

**RESPONSE:**

70. Admit that Saint Thomas Neurosurgical could have purchased Depo-medrol (or the generic version of that drug) manufactured by an FDA regulated pharmaceutical manufacturer such as Pfizer or Teva for use in epidural steroid injections.

**RESPONSE:**

71. Admit that from 2000 to the present, the medication formulary for Saint Thomas Neurosurgical lists those steroids that are acceptable for use at Saint Thomas Neurosurgical and includes: Decadron, Depo-medrol, Solumedrol and Celestone Soluspan.

**RESPONSE:**

72. Admit that the Saint Thomas Neurosurgical formulary does not include generic MPA or MPA from a compounding pharmacy as acceptable for use at Saint Thomas Neurosurgical.

**RESPONSE:**

73. Admit that the Saint Thomas Neurosurgical formulary does include and allows for the administration of MPA manufactured by Pfizer under the name Depo-medrol.

**RESPONSE:**

74. Admit that a true and correct copy of Saint Thomas Neurosurgical's written policy entitled "Formulary," as it existed in June through September of 2012, is attached as Exhibit 10.

**RESPONSE:**

75. Admit that in late 2010, Saint Thomas Neurosurgical began purchasing MPA from Clint Pharmaceuticals.

**RESPONSE:**

76. Admit that the MPA that Saint Thomas Neurosurgical purchased from Clint Pharmaceuticals came from an FDA approved manufacturer.

**RESPONSE:**

77. Admit that according to Clint Pharmaceuticals' website:

Clint Pharmaceuticals *has not, and never will*, distribute any products that are compounded. All products that are distributed by Clint Pharmaceuticals are from manufacturers that have acquired approval from the FDA. We have historically recommended that all providers DO NOT use unapproved compounded steroids especially when FDA approved products are commercially available."

**RESPONSE:**

78. Admit that Saint Thomas Neurosurgical purchased MPA from Clint Pharmaceuticals at the price of \$6.49 per 80mg vial. An invoice from Clint Pharmaceuticals dated January 26, 2011 and confirming that price is attached as Exhibit 11.

**RESPONSE:**

79. Admit that in May 2011, an NECC sales representative emailed Saint Thomas Neurosurgical's facility director, Ms. Schamberg, asking what price NECC would need to offer for MPA in order to gain Saint Thomas Neurosurgical's business. Ms. Schamberg replied that if NECC could get the price under \$6.50 per vial she would be willing to "talk" to NECC. A true and correct copy of email correspondence confirming that exchange is attached as Exhibit 12.

**RESPONSE:**

80. Admit that on June 9, 2011, Clint Pharmaceuticals increased the price to Saint Thomas Neurosurgical for MPA from \$6.49 to \$8.95 per vial, an increase of \$2.46 per vial. A true and correct copy of an Invoice from Clint Pharmaceuticals dated June 9, 2011 confirming that price increase is attached hereto as Exhibit 13.

**RESPONSE:**

81. Admit that Saint Thomas Neurosurgical was not willing to pay \$8.95 per vial of MPA from Clint Pharmaceuticals if it could be procured at a lower price from NECC.

**RESPONSE:**

82. Admit that on June 10, 2011, Ms. Schamberg on behalf of Saint Thomas Neurosurgical emailed an NECC sales representative indicating that if NECC would guarantee a price for MPA of \$6.50 per 80mg vial, Saint Thomas Neurosurgical would be willing to do business with NECC. (See Exhibit 12).

**RESPONSE:**

83. Admit that after NECC indicated its willingness to sell Saint Thomas Neurosurgical MPA for \$6.50 per 1mL 80mg vial, Ms. Schamberg obtained approval from Dr. Culclasure to begin ordering from NECC.

**RESPONSE:**

84. Admit that both Ms. Schamberg and Dr. Culclasure approved the purchases of MPA from NECC.

**RESPONSE:**

85. Admit that Saint Thomas Neurosurgical placed its first order with NECC on or about June 10, 2011. That order consisted of 500 1mL 80 mg vials of MPA and 200 2mL 80 mg vials of MPA.

**RESPONSE:**

86. Admit that a true and correct copy of the Prescription Order Form referenced in the preceding request reflecting Saint Thomas Neurosurgical's first order with NECC is attached as Exhibit 14.

**RESPONSE:**

87. Admit that the June 2011 order form attached as Exhibit 14 did not contain any patient names despite the fact that the order form included a column for that information.

**RESPONSE:**

88. Admit that as evidenced by Dr. John Culclasure's name/signature on the June 2011 order form attached as Exhibit 14, Dr. Culclasure was aware of and approved the purchase of MPA from NECC.

**RESPONSE:**

89. Admit that NECC sent invoices to Saint Thomas Neurosurgical evidencing five separate purchases by Saint Thomas Neurosurgical of five-hundred 80 mg. vials of MPA as reflected in invoices dated June 6, 2012; June 26, 2012; July 25, 2012; August 13, 2012; and August 31, 2012. A true and correct copy of those invoices is attached as Exhibit 15.

**RESPONSE:**

90. Admit that Saint Thomas Neurosurgical purchased 2,500 vials of MPA from NECC during the time period June through August 2012.

**RESPONSE:**

91. Admit that in early to mid-2012, an NECC representative informed Ms. Schamberg that NECC needed Saint Thomas Neurosurgical to submit a list of patients with each order in order to comply with Massachusetts Board of Pharmacy requirements.

**RESPONSE:**

92. Admit that Ms. Schamberg told the NECC representative that she could not predict which patients would receive MPA. The NECC representative indicated that any list of patient names would suffice.

**RESPONSE:**

93. Admit that a true and correct copy of a Saint Thomas Neurosurgical interrogatory response discussing its communications with NECC is attached as Exhibit 16.

**RESPONSE:**

94. Admit that Saint Thomas Neurosurgical provided NECC with lists of patients' names (including Mickey Mouse) with its order(s) for MPA from NECC. Saint Thomas



Neurosurgical provided those patient lists to NECC even though the patients on those lists did not necessarily receive MPA.

**RESPONSE:**

95. Admit that a redacted copy of a list of patient names submitted to NECC by Saint Thomas Neurosurgical showing the name “Mickey Mouse” is attached as Exhibit 17.

**RESPONSE:**

96. Admit that the Tennessee Department of Health and the United States Centers for Disease Control and Prevention (“CDC”) began investigating a fungal meningitis outbreak in September 2012.

**RESPONSE:**

97. Admit that several patients of Saint Thomas Neurosurgical were diagnosed with fungal meningitis after being injected with MPA procured from NECC.

**RESPONSE:**

98. Admit that on September 20, 2012, Saint Thomas Neurosurgical closed because of the fungal meningitis outbreak.

**RESPONSE:**

99. Admit that attached as Exhibit 18 is a true and correct copy of information from the CDC website located at <http://www.cdc.gov/hai/outbreaks/meningitis-facilities-map.html>.

**RESPONSE:**

100. Admit that according to the CDC, NECC recalled the following lots of methylprednisolone acetate (PF) 80mg/ml on September 26, 2012:

- Lot #05212012@68, BUD 11/17/2012;
- Lot #06292012@26, BUD 12/26/2012; and
- Lot #08102012@51, BUD 2/6/2013.

**RESPONSE:**

101. Admit that according to the CDC, Saint Thomas Neurosurgical received MPA from NECC that was from one or more of the recalled lots.

**RESPONSE:**

102. Admit that attached as Exhibit 19 is a true and correct copy of the FDA Form 483 for New England Compounding Center issued on October 26, 2012.

**RESPONSE:**

103. Admit that the FDA analyzed 50 vials from lot 08102012@51 (one of the three lots originally recalled by NECC).

**RESPONSE:**

104. Admit that the FDA confirmed the presence of viable microbial growth in 50 out of 50 vials tested from lot 08102012@51.

**RESPONSE:**

105. Admit that attached as Exhibit 20 is a true and correct copy of CDC laboratory confirmed results from three NECC MPA lots recalled on September 26, 2012.

**RESPONSE:**

106. Admit that the CDC isolated *Exserohilum rostratum* in two of the three lots of MPA originally recalled from NECC.

**RESPONSE:**

107. Admit that according to the CDC, *Exserohilum rostratum* is the same fungus as the one found in laboratory-confirmed cases of human infection.

**RESPONSE:**

108. Admit that epidural steroid injections administered to various patients at Saint Thomas Neurosurgical were contaminated with fungus.

**RESPONSE:**

109. Admit that epidural steroid injections administered to various patients at Saint Thomas Neurosurgical caused them to contract fungal meningitis. That disease caused some patients to die, and it sickened others.

**RESPONSE:**

110. Admit that fungal meningitis caused some Saint Thomas Neurosurgical patients to die.

**RESPONSE:**

111. Admit that fungal meningitis sickened some Saint Thomas Neurosurgical patients.

**RESPONSE:**

112. Admit that no facts suggest that patients who contracted fungal meningitis after receiving epidural steroid injections at Saint Thomas Neurosurgical administered during July, August and/or September of 2012 contracted that disease from any source other than those epidural steroid injections.

**RESPONSE:**

113. Admit that attached as Exhibit 21 is a true and correct copy of a print-out of an archived version of Howell Allen Clinic's website as it existed on June 18, 2012, accessed at <http://web.archive.org/web/20120618174929/http://howellallen.com/clinic/locations.php>.

**RESPONSE:**

114. Admit that as reflected on Exhibit 21, Howell Allen Clinic listed “St. Thomas Outpatient Neurosurgical Center” as one of its clinic locations as recently as June 2012.

**RESPONSE:**

115. Admit that as reflected on Exhibit 21, Howell Allen Clinic listed “St. Thomas Office” as one of its clinic locations as recently as June 2012.

**RESPONSE:**

116. Admit that attached as Exhibit 22 is a true and correct copy of a print-out of an archived version of Howell Allen Clinic’s website as it existed on June 22, 2012, accessed at [http://web.archive.org/web/20120622063123/http://howellallen.com/stThomas\\_outpatient.htm](http://web.archive.org/web/20120622063123/http://howellallen.com/stThomas_outpatient.htm)

**RESPONSE:**

117. Admit that as reflected on Exhibit 22, Howell Allen Clinic described Saint Thomas Outpatient Neurosurgical Center, LLC (“Saint Thomas Neurosurgical”) in part as follows:

“Howell Allen Clinic’s St. Thomas Outpatient Neurosurgical Center provides efficient and professional ambulatory care to have you in, out and on your way to recovery in no time.

• • •

Our physicians and nurses will make every effort to ensure that you are comfortable during this time.”

**RESPONSE:**

118. Admit that attached as Exhibit 23 is a true and correct copy of a print-out of Howell Allen Clinic's website as it existed on February 8, 2013, located at <http://howellallen.com/locations.com>.

**RESPONSE:**

119. Admit that Howell Allen Clinic removed from its "office locations" webpage, all references to St. Thomas Outpatient Neurosurgical Center after the recent fungal meningitis outbreak.

**RESPONSE:**

120. Admit that the webpage (and any corresponding link) reflected on Exhibit 22 was removed from Howell Allen Clinic's website after the recent fungal meningitis outbreak.

**RESPONSE:**

121. Admit that attached as Exhibit 24 is a true and correct copy of a brochure provided to patients by Howell Allen Clinic.

**RESPONSE:**

122. Admit that as reflected on Exhibit 24, Howell Allen Clinic listed St. Thomas Outpatient Neurosurgical Center as one of its office locations.

**RESPONSE:**

123. Admit that attached as Exhibit 25 is a true and correct copy of a billing statement from Saint Thomas Neurosurgical.

**RESPONSE:**

124. Admit that the telephone number reflected on Saint Thomas Neurosurgical's billing statement (Exhibit 25) is the same telephone number that appears on Howell Allen Clinic's website.

**RESPONSE:**

125. Admit that attached as Exhibit 26 is a true and correct copy of a billing statement from Howell Allen Clinic.

**RESPONSE:**

126. Admit that attached as Exhibit 27 is a CD containing true and correct copies of documents produced by Saint Thomas Outpatient Neurosurgical Center, LLC in the action styled: Wayne A. Reed, individually and as husband and next of kin of decedent, Diana E. Reed v. Saint Thomas Outpatient Neurosurgical Center, LLC, Howell Allen Clinic a Professional Corporation, Saint Thomas Network, Saint Thomas Health, and St. Thomas Hospital; Davidson County Circuit Court No. 13C417. Those documents are bates labeled STOPNC\_0001 – STOPNC\_0313; STOPNC\_0320 – STOPNC\_0328; STOPNC\_0335 – 0531; and STOPNC\_0533 - 0749.

**RESPONSE:**

127. Admit that attached as Exhibit 28 is a CD containing true and correct copies of photographs produced by Saint Thomas Outpatient Neurosurgical Center, LLC in the action styled: Wayne A. Reed, individually and as husband and next of kin of decedent, Diana E. Reed v. Saint Thomas Outpatient Neurosurgical Center, LLC, Howell Allen Clinic a Professional Corporation, Saint Thomas Network, Saint Thomas Health, and St. Thomas Hospital; Davidson County Circuit Court No. 13C417. Those photographs are bates labeled STOPNC\_0750 – STOPNC\_0794.

**RESPONSE:**

128. Admit that attached as Exhibit 29 is a CD containing true and correct copies of documents produced by Howell Allen Clinic in the action styled: Wayne A. Reed, individually and as husband and next of kin of decedent, Diana E. Reed v. Saint Thomas Outpatient Neurosurgical Center, LLC, Howell Allen Clinic a Professional Corporation, Saint Thomas Network, Saint Thomas Health, and St. Thomas Hospital; Davidson County Circuit Court No. 13C417. Those documents are bates labeled HAC\_005 – HAC\_029.

**RESPONSE:**



Dated: October 9, 2013

/s/ J. Gerard Stranch, IV

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**CERTIFICATE OF SERVICE**

I, J. Gerard Stranch, IV, hereby certify that on the 9th day of October, 2013, the foregoing document was served via hand delivery (\*), electronic mail (\*\*), and/or U.S. Mail, postage prepaid, on the following counsel:

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